LIVERPOOL JOHN MOORES UNIVERSITY PARTICIPANT INFORMATION SHEET

Title of Project. "A time-course profile of exercise-induced gastrointestinal damage".

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School: Liverpool John Moores University

You are being invited to take part in a research study. Before you decide it is important that you understand why the research is being done and what it involves. Please take time to read the following information. Ask us if there is anything that is not clear or if you would like more information. Take time to decide if you want to take part or not.

You MUST NOT take part in this study if:

- You are younger than 18 or older than 50 years.
- You are a current smoker
- You are diagnosed with uncontrolled asthma
- Currently unwell with cold or flu
- You have a current musculoskeletal injury.
- Are currently or have taken any form of prescription medication IN PAST 4 WEEKS.
- Been told you have liver disease
- Have gastric or duodenal ulcers
- Have been diagnosed as having a gastrointestinal disease
- Have kidney problems
- Have a chronic connective tissue disorder

- Have heart disease or problems with your heart
- Have suffered cerebrovascular disease such as a stroke
- Are taking balcofen, methotrexate, tacrolimus and voriconazole, beta-blockers or diuretics drugs.
- Refuse to be compliant to abstention from exercise on the 24 hrs prior to experimental assessment
- Refuse to be compliant to the abstention from non-steroidal anti-inflammatory drugs (NSAIDs; e.g. ibuprofen) on the 48 hrs prior to experimental assessment
- Refuse to be compliant to the abstention from alcohol on the 24 hrs prior to experimental assessment

1. What is the purpose of the study?

The purpose of the research is to assess the effect of performing endurance exercise on consecutive gastrointestinal integrity. There is some evidence to suggest that intestinal permeability (commonly known as leaky gut) is increased following a single bout of endurance exercise. However, to date it is not known at which point of a matched exercise protocol that maximal permeability occurs

2. Do I have to take part?

No, you do not have to participate, if you do not wish to. It is up to you to decide, whether or not to take part in this research study. If you do want to take part, you will be given this information sheet to read and ask any questions in order that you clearly understand what you are being asked to do. You will need to sign a consent form if you are clear about the study procedures and are happy to participate. You are still free to withdraw from the study at any time and without giving a reason. A decision to withdraw will not affect your rights/any future treatment/service you receive. Please ensure you have carefully read all information and asked any questions no matter how small they may seem regarding your participation.

3. What will happen to me if I take part?

All research for the study will take place in the LJMU laboratories, and you will be required to make **4 visits** to the laboratory. Each of these visits will last between **1 and 2 hours**. During the

first visit, you will be invited to complete an incremental treadmill running test to exhaustion to assess VO_2max. This will involve;

• Running at a very low intensity which will become progressively harder every two minutes. Initially the speed will 8 $km \cdot h^{-1}$ increasing by 2 $km \cdot h^{-1}$ until 16 $km \cdot h^{-1}$ then the speed will be held constant with the gradient then increasing by 2 % every 2 minutes. The aim is to run until you can no longer keep going. During the test we will measure the amount of oxygen you use and CO_2 you give out via a face mask attached to your face. We will measure how hard your heart is working via a polar belt fitted around your chest. At the start and end of the test we will measure blood lactate concentrations via a small finger prick.

The 3 remaining visits will consist of exercise days, each separated by 7 days. During each of these exercise days you will be invited to complete a 60min treadmill run at a pace equivalent to your 70% VO_2 max. You will be required to rest each day prior to exercise and not perform intense exercise between trials.

On all exercise days of the study, you will be invited to consume a drink containing a sugar solution diluted in water and insert a **rectal thermometer** for assessment of core temperature during the exercise. Heart rate will also be recorded using a chest strap heart rate monitor. The solution contains two non-toxic sugars which are used to assess the leakiness of the gut. In a random order, you will be invited to ingest the sugar solution at the start, during or at the end of the treadmill run. The dose 10g and 2 g is used commonly and is unlikely to cause any potential side effects (possible loose stools, flatulence) . To assess the intensity of the exercise and the levels of these sugars that have “leaked” from your digestive system, 4 venous blood samples will be taken via vena puncture, one immediately pre- and post-exercise, one 60 minutes post-exercise and then and one at 2hrs following ingesting of the sugars. The total volume of blood taken during each exercise visit is approximately 40mL, the equivalent of 8 teaspoons.

4. Are there any risks, discomforts, benefits involved?

There are a number of discomforts and risks that you need to be aware of in your consideration of participating in this research process. These are:

- The VO_2 max fitness test performed requires you to run to exhaustion and put in maximum effort which may cause discomfort and make you tired. Following this test, you may also have muscle soreness. - The use of a needle to draw blood can be uncomfortable and may leave a small bruise

upon removal. This process will be repeated four times during each visit. - The Gut permeability sugar probes are natural sugar products as such they are considered safe. There is a mild risk of diarrhoea and increased flatulence as a result of ingestion. - Insertion of the rectal thermometer can be uncomfortable but they are considered safe.

Benefits of the study include:

In participating in this study no direct benefit to you will occur. We will provide performance tests to determine your maximal exercise capacity, and heart rates for running training zones. Whilst participating you may experience and learn about ideas around gut function and exercise these ideas at present are unconfirmed. **We will be unable to provide direct information to you on the leaky gut responses you may experience as our test are not authorised to provide information leading to a clinical diagnosis.**

5. Will my taking part in the study be kept confidential?

Should you decide to participate in the study, your confidentiality will be assured in a number of ways:

Secure file storage – all data files will be stored on computers or laptops with passwords that are only know by the research team.

Rather than using your name to label data files and samples collected, you will be given a participant number, which will only be known by you and the research team. This way none of the other participants or anyone outside of the research team will be able to identify which test data belongs to you.

No files containing data about you will be kept anywhere that outside parties will be able to see them. **Cause for Complaint.** If you have any reason to be unhappy with how your participation has gone in this study please contact the project supervisor on the email address listed below. **This study has received ethical approval from LJMU's Research Ethics Committee 18/SPS/003**

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If you any concerns regarding your involvement in this research, please discuss these with the researcher in the first instance. If you wish to make a complaint, please contact researchethics@ljmu.ac.uk and your communication will be re-directed to an independent person as appropriate.